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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/729,343	LEE ET AL.	
	Examiner	Art Unit	
	Sharmila Gollamudi Landau	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7,9-16 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 7, 9-16, and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed 5/16/07 is acknowledged. Claims 1, 3, 7, 9-16, and 25 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claims to recite, "less than 2% by weight of carbonate ions incorporated into the calcium phosphate crystal structure", which does not have support in the specification. It is noted that applicant argues that the examples teach 0.5-1.56% carbonate ions; however this does not provide support for "less than 2%" since less than 2% includes values such as 1.99%, 1.98%, etc.

Claim Rejections - 35 USC § 102

The rejection of claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by RE 33,221 to Brown et al is withdrawn in light of the amendments filed 5/16/07 limiting carbonate ions to less than 2%.

The rejection of claims 1, 3, 7, and 9-12 under 35 U.S.C. 102(e) as being anticipated by Constantz (5,962,028) is withdrawn in light of the amendments filed 5/16/07 limiting carbonate ions to less than 2%.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over RE 33,221 to Brown et al.

Brown et al teach a dental restorative cement pastes. The cements are used for conventional purposes, i.e. to fill a tooth socket, a replacement cone, a cement for implanting and replanting teeth, a material which promotes bone growth, bone implants or prostheses. See column 9, lines 20-40. The composition is a mixture of two sparingly soluble calcium phosphates and a dilute aqueous solution. The calcium phosphate source is selected from amorphous, crystalline, or cryptocrystalline sources. The combination hardens into dental cement when

contacted with living tissue. See abstract. The CaP mix contains tetracalcium phosphate and at least one sparingly soluble calcium phosphate, i.e. dicalcium phosphate dehydrate or brushite. See column 3, lines 35-50. The composition may be in a slurry, gel, cement, or injectable form. See example 3. Table II provides the instant setting times. Brown et al disclose methods of manipulating setting times by adding a sizable amount of hydroxyapatite seed crystals to the paste to facilitate crystal formation. Further, crystal habit modifiers such as magnesium, citrates, or phosphonates may be used to promote expansion and adhesion. These modifiers absorb onto the specific sires of the crystal surfaces during growth affecting the morphology of the crystals. Further, appropriate combinations of varying particle sizes promote setting expansion. These modifiers includes Mg2+, Sr2+, citrate, phosphonates, carbonate, polyphosphates, sucrose phosphate and phosphocitrate up to 1%. These modifiers absorb onto the specific sites of the crystal surfaces during growth, thereby affecting the morphology of the crystals. Additionally, appropriate combinations of varying or "gap-graded" particle sizes would promote setting expansion. See column 9, line 55 to column 10, line 5. Example 3 further teaches the manipulation of the setting time. The rate of remineralization may also be adjusted which affects the body's ability to resorb the material. Table 11 discloses the instant hardening time. Therefore rapid mineralization is beneficial under some circumstances such as incipient dental caries and lesions. Slow mineralization is beneficial for deep lesions. See column 8, lines 25-47. Brown discloses the instant composition is more porous and invaded by organic bone tissue (resorbable). See column 12, lines 40-50.

Brown suggests the use of carbonate but does not exemplify it.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance provided by Brown and incorporate up to 1% of carbonate ions. One would have been motivated to do so since Brown suggests the incorporation of crystal modifiers such as carbonate ions up to 1% to change the morphology of the crystals and change the setting expansion of the paste.

With regard to the recitation of "non-stoichiometric", using a crystallization modifier such as carbonate would render a non-stoichiometric proportion.

Claims 1, 3, 7, and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz (5,962,028).

Constantz teaches a carbonated hydroxyapatite (HA) which is resorbable and a flowable mass that may be administered via a syringe and harden in situ. See abstract and column 4, line 33-35. The carbonated HA is non-stoichiometric, i.e. poorly crystalline, wherein the Ca/P ratio is as low as 1.33. See column 4, lines 57-65. The composition ha a consistency of putty and may be molded prior to setting. Hardening usually takes at least about 5 minutes, more preferably at least about 15 minutes, and not more than about 20 minutes. See column 6, lines 25-45. The composition is administered at a physiological temperature of 37 degree C. see column 50-61. The composition is applicable as bone cements or fillers (reads on claim 11), dental or endodontic fillers (reads on claim 10), coatings for bioimplantable substrates, or formed into a suitable shape before or after hardening into a monolithic structure (reads on claim 12). See column 8, lines 1-5. Constantz teaches using ***about 2%*** to about 10% of carbonate.

With regard to the functional limitation of claim 1 and 9, i.e. the resorption rate, it is the examiner's position that since Constantz teaches a similar product, the resorption rate will be inherent.

With regard to claim 7, although Constantz does not specify the x-ray pattern, it is the examiner's position that the prior art has a similar differential pattern as that of instant invention since the Constantz teaches a similar product, i.e. a poorly crystalline apatitic calcium phosphate. "Poorly crystalline apatite" as defined by the specification is at least one gram of PCA material is implanted, undergoes ossification in the body, and is resorbed. Further, Constantz discloses the product is similar to native bone (see column 2) and natural bone contains carbonate; thus the prior art must have a similar X-ray diffraction pattern.

Constantz teaches the composition is applicable as bone cements or fillers, dental or endodontic fillers, coatings for bioimplantible substrates, or formed into a suitable shape before or after hardening into a monolithic structure. See column 8, lines 1-5.

Although Constantz teaches about 2% carbonate ions as the lower limit, Constantz does not teach the lower limit of less than 2%. Further, the reference does not specifically teach the instant implant sites.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance provided by Constantz and manipulate the amount of carbonate ions. It is noted that less than 2% includes 1.9999%, thus it is within the skill of an artisan to manipulate the amount of carbonate during routine optimization and experimentation. It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the

optimum percentage. See In re Boesch, 617 F.2d 272, 276,205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In re Paterson Appeal No. 02-1189 (Fed. Cir. January 8, 2003)

Further, it would have been obvious to utilize the composition in the desired implant site. One would have been motivated to do so since Constantz teaches the instant composition as a variety of functions including a bone cements or fillers or formed into a suitable shape before or after hardening into a monolithic structure. Thus, depending on the area that required the composition, one would have been motivated to implant it at the given site. For instance, if one desired a bone filler for low-density bone such as osteoporotic bone, one would have been motivated to fill osteoporotic bone.

Response to Arguments

Applicant argues that Constantz does not teach or suggest the limitations of claim 1 and thus is not obvious.

Applicant's arguments filed 5/16/07 have been fully considered but they are not persuasive. Firstly, it is the examiner's position that the recitation "less than 2%" is new matter. Secondly assuming arguendo that applicant has support for such a limitation, the examiner points 3 out that less than 2% includes the values of 1.99%, 1.98%, etc. and Constantz teaches ***about*** 2%. Therefore, it is the examiner's position that it is within the skill of an artisan to determine the optimal amount during routine experimentation absent evidence of the unexpectedness of the instant concentration.

Therefore, Constantz renders the instant invention obvious.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz (5,962,028) in view of Ison et al (5,683,496).

The teachings of Constantz have been delineated above. Constantz teaches the composition comprises carbonate, acid phosphate source, and a calcium source such as tricalcium phosphate, tetracalcium phosphate, etc. The composition is made by reacting an acidic phosphate source and a basic calcium source. Example 2 teaches a composition comprising monobasic calcium phosphate monohydrate(acidic phosphate source), tetracalcium phosphate (calcium source), calcium carbonate, calcium oxide, and orthophosphoric acid. Note that the carbonate causes the calcium phosphate to be poorly crystallized.

Constantz does not teach the use of amorphous calcium phosphate as the calcium source to make the carbonated hydroxyapatite.

Ison teaches storage stable calcium phosphate cement. The cement is a moldable paste that is applied to the bone site to provide a bone-like structure. See column 1, lines 30-45. Ison teaches the calcium phosphate ratio depends on the type of cement desired. If a carbonated hydroxyapatite is desired, a cement having a Ca/P ratio is 1.33 to 2. The composition is made by reacting an acidic phosphate source and a basic calcium source. See column 3-4. The calcium source is selected from tetracalcium phosphate, tricalcium phosphate, or amorphous calcium phosphate and the acidic phosphate source may be monobasic calcium phosphate monohydrate. See column 3, lines 15-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Constantz '028 and Ison and utilize amorphous calcium

phosphate as the calcium source. One would have been motivated to do so since Ison teaches the equivalency of tricalcium phosphate, tetracalcium phosphate, and amorphous calcium phosphate, as the calcium source in making a carbonated hydroxyapatite implant.

Response to Arguments

Applicant argues that Constantz does not teach or suggest the limitation "less than 2%" carbonate ions.

Applicant's arguments filed 5/16/07 have been fully considered but they are not persuasive. The merits of Constantz have been discussed above and are incorporated herein. Since applicant has not provided any substantive arguments to the instant rejection of Constantz in view of Ison, the combination is considered to render the instant claims obvious.

Claims 1, 3, 7, 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/02412 to Simkiss et al.

Simkiss et al teach an amorphous calcium phosphate mixed with a crystal inhibitor that hardens to form bone in vivo. See abstract. A mixture of amorphous calcium phosphates may be used with different transformation rates wherein amount of the inhibitor effects the crystallinity of the material. See page 6. The precursor material is applied to the site where bone growth is required. See page 3. Simkiss teaches hydroxyapatite Ca5(OH)PO4)3 on page 1 as the inorganic material of choice. The molar ratio of Ca to P is 1.67. Tricalcium phosphate is also taught which has a molar ratio of 1.5. Negligible amounts of magnesium in the composition (as low as 0.001 moles for 1 mole calcium). It should be noted that compositions containing hydroxyapatite or tricalcium phosphate having magnesium and tricalcium phosphate are known to be resorbable and are not poorly crystalline since the magnesium prevents full crytallization. Simkiss

exemplifies a material wherein the material is hardened after "many hours". See page 4. However, Simkiss also teaches the ability to modify the transformation rates when the material is exposed to body fluid, by including crystallization inhibitors such as pyrophosphate or magnesium ions in certain proportions. See page 2, last paragraph. Simkiss teaches the precursor material contains the inhibitors in low levels, which inhibit the crystallization of the material, and when the implant is in vivo, the inhibitors are leached away by body fluid, thus causing the precursor material to undergo transformation into crystalline hydroxyapatite. See page 3. On page 6, Simkiss teaches transformation time can be controlled by the choice of inhibitor and the choice of inhibitor concentration and/or solubility. A slow mechanism is taught as one requiring natural bone formation and repair mechanism. However, fast-setting material may be used depending on the intended use such as bone filling or bone-grafting. See page 6. X-ray diffraction patterns are seen in Figure 1.

Simkiss does not teach the recited setting time.

However, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Simkiss and formulate a fast-setting precursor material. One would have been motivated so depending on the intended use of the implant. For instance, Simkiss teaches the use of fast setting for uses such as bone filling whereas if natural bone formation is desired, one would utilize a slow-setting material. Therefore, the motivation to manipulate the parameters of the prior art depends on the intended use of the implant and treatment plan. Furthermore, Simkiss provides guidance on how to formulate the desired setting rate by stating that a higher concentration of crystallization inhibitor provides for a slow-rate and less of the inhibitor provides for a fast rate. It should be further noted that the instant claims

recite "hardened within..." but do not recite the degree of hardness. For instance, Simkiss exemplifies a product that takes hours to completely hardened, however the start of the hardening process could fall within applicant's range. Lastly, it should be noted that it is the examiner's position that since Simkiss teaches similar precursor material without distinction, the functional limitation, i.e. the resorption rate will be implicit. However, if applicant argues otherwise, then the applicant has the burden of proving otherwise.

With regard to the limitation "less than 2% carbonate ions", the examiner points out that less than 2% includes the value 0. The examiner has withdrawn the rejection over claim 25 since claim 25 requires a carbonated paste; thus the value cannot be 0.

With regard to the recitation of "non-stoichometric", Simkiss teaches using a crystallization inhibitor such as magnesium with the amorphous calcium phosphate to prevent complete crystallization of the amorphous calcium phosphate. Thus, Simkiss' material is not completely crystallized since it contains a crystallization inhibitor. Therefore, the material also cannot be in stoichiometric proportion.

Response to Arguments

Applicant argues that Simkiss does not teach or suggest incorporating carbonate in any amount.

Applicant's arguments filed 5/16/07 have been fully considered but they are not persuasive. As discussed in the rejection, the recitation of "less than 2% carbonate" includes the value zero since applicant the claim does not require carbonate. The scope of the claim is interpreted to be devoid of carbonate or if the composition has carbonate, the concentration must be less than 2% carbonate. The examiner suggests amending the claims to "carbonated synthetic

poorly crystalline apatitic". For instance, claim 25 requires a carbonated paste wherein the concentration of carbonate is less than 2%; hence the amount of carbonate cannot be zero.

Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/02412 to Simkiss et al in view of RE 33,221 to Brown et al.

Simkiss et al teach an amorphous calcium phosphate that hardens to form bone in vivo. See abstract. The precursor material is applied to the site where bone growth is required. See page 3. Simkiss teaches hydroxyapatite Ca5(OH)PO4)3 on page 1 as the inorganic material of choice. The molar ratio of Ca to P is 1.67. Tricalcium phosphate is also taught which has a molar ratio of 1.5. Negligible amounts of magnesium in the composition (as low as 0.001 moles for 1 mole calcium). It should be noted that compositions containing hydroxyapatite or tricalcium phosphate having magnesium and tricalcium phosphate are known to be resorbable. Simkiss exemplifies a material wherein the material is hardened after "many hours". See page 4. However, Simkiss also teaches the ability to modify the transformation rates when the material Is exposed to body fluid, by including crystallization inhibitors such as pyrophosphate or magnesium ions in certain proportions. See page 2, last paragraph. Simkiss teaches the precursor material contains the inhibitors in low levels, which inhibit the crystallization of the material, and when the implant is in vivo, the inhibitors are leached away by body fluid, thus causing the precursor material to undergo transformation into crystalline hydroxyapatite. See page 3. On page 6, Simkiss teaches transformation time can be controlled by the choice of inhibitor and the choice of inhibitor concentration and/or solubility. A slow mechanism is taught is one required natural bone formation and repair mechanism. However, fast-setting material may be used

depending on the intended use such as bone filling or bone-grafting. See page 6. X-ray diffraction patterns are seen in Figure 1.

With regard to claims 1, 3, 7, 9-16, Simkiss does not teach the recited setting time. With regard to claim 25, Simkiss does not teach carbonate as the crystal inhibitor and Simkiss does not teach the recited setting time.

Brown et al disclose dental restorative cement pastes. The cements are used for conventional purposes, i.e. to fill a tooth socket, a replacement cone, a cement for implanting and replanting teeth, a material which promotes bone growth, etc. see column 9, lines 20-40. The composition is a mixture of two sparingly soluble calcium phosphates and a dilute aqueous solution. The combination hardens into dental cement when contacted with living tissue. See abstract. The CaP mix contains tetracalcium phosphate and at least one sparingly soluble calcium phosphate, i.e. dicalcium phosphate dehydrate or brushite. See column 3, lines 35-50. The composition may be in a slurry, gel, cement, or injectable form. See example 3. Table II provides the instant setting times. Brown et al disclose methods of manipulating setting times by adding a sizable amount of hydroxyapatite seed crystals to the paste to facilitate crystal formation. Further, crystal habit modifiers (up to 1%) such as carbonate, magnesium, citrates, or phosphonates may be used to promote expansion and adhesion. These modifiers absorb onto the specific sites of the crystal surfaces during growth affecting the morphology of the crystals. Further, appropriate combinations of varying particle sizes promote setting expansion. See column 9, line 55 to column 10, line 5. Example 3 further teaches the manipulation of the setting time. The rate of remineralization may also be adjusted which affects the body's ability to resorb the material. Therefore rapid mineralization is beneficial under some circumstances such as

incipient dental caries and lesions. Slow mineralization is beneficial for deep lesions. See column 8, lines 25-47.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Simkiss et al and Brown et al and manipulate Simkiss's formulation to yield a fast-setting precursor material. One would have been motivated so since Brown et al also teach a calcium phosphate injectable composition that has setting capabilities at physiological temperatures. Further, Brown provides guidance on how to manipulate the setting condition by changing the amount of hydroxyapatite, adding crystal modifiers such as magnesium, phosphonates, and citrates, which also taught by Simkiss for the same purpose of manipulating setting time. Therefore, it can be seen that manipulation of setting times is a conventional practice done in the art at the time the invention was made. Lastly, one would have been motivated to manipulate the parameters of the prior art depending on the intended use of the implant and treatment plan as taught by both Simkiss and Brown et al.

With regard to claim 25, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize carbonate in the composition in an amount of less than 2%. One would have been motivated to do so since Simkiss teaches the use of crystallization inhibitors such as magnesium or phosphonates to modify the transformation rates and Brown teaches the use of carbonate, magnesium, and phosphonates of (up to 1%) as crystal modifiers. Therefore, it would have been obvious to substitute one crystal modifiers with another with a reasonable expectation of success since the prior art teach both function in the same manner.

Response to Arguments

Applicant argues that Simkiss does not teach or suggest incorporating carbonate in any amount and Brown does not cure this deficiency.

Applicant's arguments filed 5/16/07 have been fully considered but they are not persuasive. As discussed in the rejection, the recitation of "less than 2% carbonate" includes the value zero since applicant the claim does not require carbonate. The scope of the claim is interpreted to be devoid of carbonate or if the composition has carbonate, the concentration must be less than 2% carbonate. The examiner suggests amending the claims to "carbonated synthetic poorly crystalline apatitic". For instance, claim 25 requires a carbonated paste wherein the concentration of carbonate is less than 2%; hence the amount of carbonate cannot be zero.

With regard to claim 25, as discussed in the rejection, it is the examiner's position that it is within the skill of an artisan to substitute one crystal modifier with another absent evidence of the unexpectedness of using carbonate ions specifically.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1, 3, 7, 9-16, and 25 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,214,368, claims 1-2 of U.S. Patent No. 6,132,463, claims 1-21 of U.S. Patent No. 6,027,742, claims 1-9 of U.S. Patent No. 6,331,312 are maintained for the reasons set forth in the Office Action of April 23, 2003.

Response to Arguments

Applicant states that upon allowance of the instant claims, the applicant may consider filing of a Terminal Disclaimer to overcome the rejection. Accordingly, the rejection is maintained.

Claims 1, 3, 7, 9-16, and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-55 of U.S. Patent No. 6,541,037, claims 12-19 and 21 of U.S. Patent No. 6,214,368, claims 1-27 of U.S. Patent No. 6,277,151.

The instant application id directed to a method of treating a bone defect by providing a resorbable PCA calcium phosphate that is injectable and hardened within 10-60 minutes. At least 80% is resorbed in one year. Claim 25 is directed to a method of prosthetic device by applying a paste comprising amorphous calcium phosphate, PCA calcium phosphate, and a fluid wherein hardened within 10-60 minutes.

US '037 is directed to a method of delivering a active agent comprising providing a paste composition with an injectable consistency comprising amorphous calcium phosphate, an acidic calcium phosphate (selected from claim 42 including instant PCA calcium phosphate), and solution wherein the composition is applied and allowed to harden with an endothermic process.

The same Ca/P ratio is claimed; the same hardening time is claimed, and the same resorption rate is claimed.

US '368 is directed to a method of promoting bone growth, comprising: providing a paste, said paste comprising a calcium phosphate powder, said powder comprising a first calcium phosphate material having at least 90% amorphous character and an acidic second calcium phosphate material (selected from claim 19 including instant PCA calcium phosphate), the powder having a calcium to phosphorous molar ratio in the range of about 1.2 to 1.68, and a fluid in an amount which provides a formable or injectable consistency, said paste remaining injectable or formable for a time greater than about 60 minutes at about 22.degree. C.; applying the paste to a site requiring bone growth: and allowing the paste to harden at the site within about 30 minutes. It is the examiner's position that the composition would have the same functional limitations as the instant composition since both compositions are the same.

US '151 is directed to a method of growing collagen in vivo comprising hydrating a composition into a site comprising a amorphous calcium phosphate, a precursor (selected from claim 10 including instant PCA calcium phosphate), and a solution. The ACP is converted into a PCA calcium phosphate. The same Ca/P ratio is claimed and the same hardening time is claimed. It is the examiner's position that the composition would have the same functional limitations as the instant composition since both compositions are the same.

Accordingly, instant application and US patents are directed to similar subject matter. It is noted that although the US patents does not claim the specific implant site as claimed in claims 10-16, this is a obvious parameter wherein it is known to implant a substitute bone composition in the area that requires the implant.

Response to Arguments

Applicant states that upon allowance of the instant claims, the applicant may consider filing of a Terminal Disclaimer to overcome the rejection. Accordingly, the rejection is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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